

Department of Pesticide Regulation



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Pete Wilson Governor

MEMORANDUM

TO: John Ross, Senior Toxicologist

HSM-98002

Worker Health and Safety Branch

FROM: Tom Thongsinthusak, Staff Toxicologist

Worker Health and Safety Branch [original signed by Tom Thongsinthusak]

DATE: June 29, 1998

SUBJECT: Revised EPTC Exposure Mitigation Document

Attached is a revised document for EPTC exposure mitigation measures. In the August 8, 1995 version of this document, engineering controls were emphasized. However, in the current document a coverall or rainsuit, half-face respirator as well as reduced duration and frequency of exposure were applied for different work tasks. The option of replacing the additional personal protective equipment (PPE) with engineering controls makes the proposal consistent with the Federal Worker Protection Standard for agricultural pesticides. The margin of safety for before and after mitigation and proposed PPE are shown in this document.

If you have any comments or questions, please let me know.

Attachment

cc: Paul Gosselin John Sanders Roy Rutz Sue Edmiston

(TCW/Mitigate/HSM-98002)

APPENDIX B MITIGATION OF EPTC EXPOSURE June 29, 1998

The Department of Pesticide Regulation evaluated health risks associated with exposure to EPTC from handling activities and dietary sources. EPTC was identified by the Department to cause, in experimental animals, neurotoxicity from acute exposure, nasal cavity degeneration/hyperplasia and blood coagulation abnormality from short-term exposure, and neuromuscular degeneration from moderate-term exposure. For the purpose of the risk assessment process, dietary and occupational exposure estimates were calculated as absorbed daily dosage (ADD) for acute exposure, seasonal average daily dosage (SADD) for short-term exposure, and annual average daily dosage (AADD) for moderate-term exposure.

The Medical Toxicology Branch determined the acute and chronic potential dietary exposure of the general population and population subgroups. The highest potential dietary exposure used in the risk assessment was obtained for males aged 13-19 years; the exposure levels (μ g/kg/day) were: 1.2 for ADD; 1.2 for SADD; and 0.5 for AADD (Meierhenry, 1995). The EPTC exposures for mixer/loaders (M/L), applicators (A), and mixer/loader/applicators (M/L/A) were estimated by the Worker Health and Safety Branch (Brodberg and Thongsinthusak, 1995). The ranges of occupational exposure estimates (μ g/kg/day) were: 1.67-221 for ADD; 0.79-78.0 for SADD; 0.04-3.94 for AADD. The combined dietary and occupational exposure data and resulting margin of safety (MOS) prior to mitigation are summarized in Table 1.

The exposure level to EPTC, either from dietary or occupational or a combination of both, is generally believed to be acceptable when an MOS is 100 or greater. The MOS is derived by dividing a no-observed-effect level (NOEL) by an appropriate exposure estimate. If an MOS is less than 100, mitigation of EPTC exposure is indicated. The target levels of exposure to achieve an MOS of 100 are: $200 \,\mu g/kg/day$ for neurotoxicity (acute exposure); $7.0 \,\mu g/kg/day$ for nasal cavity degeneration/hyperplasia or blood coagulation abnormality (short-term exposure); and $5.0 \,\mu g/kg/day$ for neuromuscular degeneration (moderate-term exposure). Exposure mitigation appeared necessary for the majority of work tasks, except for exposures of applicators during chemigation by a water-run, or pilots during aerial application of granular formulation.

It is quite common that a pest control operator (PCO) or a farmer's employee performs all work activities mixing/loading and applying EPTC. The combined M/L/A exposure data were collected in a study conducted by Knarr and Iwata (1986); the results were reviewed and summarized by Brodberg and Thongsinthusak (1995). The occupational exposure of the combined M/L/A cannot be used to calculate the individual M/L and A work activities for the purpose of mitigation. Therefore, the exposure estimate for a M/L/A was subdivided into the exposure estimates for M/L and A for the purpose of mitigation. The exposure estimate of M/L/A and how the exposure data was subdivided for mixing/loading and applying activities are shown in Table 2. The EPTC exposure estimate for a M/L was obtained from a study conducted by Ross *et al.* (1986) which was subsequently reviewed by Brodberg and Thongsinthusak (1995). An exposure time period required for a mixing/loading activity was about one hour and that for application was about seven hours in a typical 8-hour workday (Ross *et al.*, 1986). Dermal

exposure for a M/L was adjusted to reflect a maximum label rate of 3.9 lbs a.i./acre for use in potatoes.

Mitigation measures for those work tasks were based upon the use of personal protective equipment (PPE) and the specific duration and frequency of exposure per workday, season or per year. The reduced duration and frequency of exposure were applied to the majority of work tasks. However, the duration of exposure for pilots and flaggers were eight hours instead of four hours, which was previously used in the estimation of exposure. It was assumed that workers for these two work tasks may work eight hours per workday and that the exposure mitigation for these work tasks was possible.

The mitigated values for ADD, SADD, and AADD and their respective MOS are shown in Table 2. In this case whenever an MOS is at or greater than the target level for SADD, it will also be acceptable for ADD and AADD because the NOEL for SADD drives the mitigation. It appeared that PPE is not required for an applicator of granular product after reducing from eight to seven workdays per season. The MOS for other work tasks are at or greater than the target level of 100. The recommended duration and frequency of exposure and requirements for PPE are shown in Table 3. Default protective values used in exposure mitigation and the method used in the calculation of ADD, SADD, and AADD are shown in Table 4.

Conclusion:

The recommended exposure mitigation measures consist of the use of specified PPE and duration and frequency of exposure. The mitigated exposures for all work tasks give an MOS at or greater than the target level of 100. Engineering controls can be used whenever they are appropriate to replace PPE based upon criteria given in the Worker Protection Standard (U.S. EPA, 1993).

References

- Brodberg, B. K., and Thongsinthusak, T. 1995. Estimation of exposure of persons in California to pesticide products containing EPTC. Worker Health and Safety Branch, Department of Pesticide Regulation.
- Meierhenry, E. 1995. Risk Characterization Document. Medical Toxicology Branch, Department of Pesticide Regulation.
- Ross, J. H., Leber, A. P., Lucas, F. D., and Chun, F. A. 1986. EPTC, mixer/loader/applicator studies for the reevaluation of EPTC. Department of Pesticide Regulation. Pesticide Registration Document Number 117-063.
- Knarr, R. D., and Iwata, Y. I. 1986. Applicator exposure to EPTC during ground-spray application of EPTAM[®] 7-E selective herbicide to potato fields. Department of Pesticide Regulation. Pesticide Registration Document Number 117-064.

- Thongsinthusak, T., Ross, J. H., and Meinders, D. 1993. Guidance for the preparation of human pesticide exposure assessment document. HS-1612. Worker Health and Safety Branch, Department of Pesticide Regulation (May 4, 1993).
- U.S. EPA. 1993. The Worker Protection Standard for Agricultural Pesticides How to Comply. United States Environmental Protection Agency, Prevention, Pesticides, and Toxic Substances. EPA 735-B-93-001.

Table 1. EPTC exposure estimates for mixer/loaders, applicators, mixer/loader/applicators, farmers' employees, and flaggers^a

		Exposure	(µg/kg/day)				
		(µg/person/day)	ADD (MOS) ^c	SADD (MOS) ^c	AADD (MOS) ^c		
A. Liquid for	rmulation: gr	ound application					
M/L^b	Dermal ^d	14664	38.23	17.99	0.84		
	Inhalation	600	8.57	4.03	0.19		
	Dietary ^e		1.20	1.20	0.50		
	Total	15864	48.00 (417)	23.22 (30)	1.53 (328)		
A^b	Dermal ^d	6244	16.28	7.66	0.36		
	Inhalation	532	3.80	1.79	0.08		
	Dietary ^e		1.20	1.20	0.50		
	Total	6776	21.28 (940)	10.65 (66)	0.94 (532)		
M/L/A ^b	Dermal ^d	27628	72.03	33.90	3.16		
(PCO)	Inhalation	2480	17.71	8.34	0.78		
	Dietary ^e		1.20	1.20	0.50		
	Total	30108	90.94 (220)	43.43 (16)	4.43 (113)		
Farmers'	Dermal ^d	27628	72.03	33.90	3.16		
employee	Inhalation	2480	17.71	8.34	0.78		
$(M/L/A)^b$	Dietary ^e		1.20	1.20	0.50		
	Total	30108	90.94 (220)	43.43 (16)	4.43 (113)		
B. Granular	formulation:	B.1 flowers/ornamer	<u>ıtals</u>				
L/A ^f	Dermal ^d	4840	12.62	5.94	0.28		
	Inhalation	240	1.71	0.81	0.04		
	Dietary ^e		1.20	1.20	0.50		
	Total	5080	15.53 (1288	7.94 (88)	0.81 (614)		
B. Granular	formulation.	B.2 aerial application	<u>1</u>				
Pilots ^g	Dermal ^d	338	0.88	0.42	0.02		
	Inhalation	110	0.79	0.37	0.02		
	Dietary ^e		1.20	1.20	0.50		
	Total	448	2.87 (6974	1.98 (353)	0.54 (932)		

Table 1 (cont.). EPTC exposure estimates for mixer/loaders, applicators, mixer/loader/applicators, farmers' employees, and flaggers^a

		Exposure				
	(μg/person/day)		ADD (MOS) ^c	SADD (MOS) ^c	AADD (MOS) ^c	
B. Granular f	formulation.	B.2 aerial application				
Flaggers ^g	Dermal ^d	2886	7.53	3.54	0.16	
	Inhalation	122	0.87	0.41	0.02	
	Dietary ^e		1.20	1.20	0.50	
	Total	3008	9.60 (2084	5.15 (136)	0.68 (731)	
Loaders ^g	Dermal ^d	21202	55.3	26.01	1.21	
	Inhalation	4180	29.9	14.05	0.65	
	Dietary ^e		1.2	1.20	0.50	
	Total	25382	86.4 (232)	41.26 (17)	2.37 (211)	
C. Chemigati	ion. C.1 wat	er-run				
Applicators ^g	Dermal ^d	2354	4.91	2.02	0.09	
11	Inhalation	60	0.43	0.18	0.01	
	Dietary ^e		1.20	1.20	0.50	
	Total	2414	6.54 (3059	3.40 (206)	0.60 (830)	
C. Chemigation. C.2 center-pivot sprinkler system						
$M/L/A^g$	Dermal ^d	84400	220	77.66	3.62	
	Inhalation	138	0.99	0.35	0.02	
	Dietary ^e		1.20	1.20	0.50	
	Total	84538	222 (90)	79.21 (9)	4.13 (121)	

a from HS-1531 (Brodberg and Thongsinthusak, 1995). Assumed M/L and A (liquid formulation), loader/applicators (ground application of granules), and applicators (water-run chemigation) worked 8 hours/day, 8 days/17-day season, and 8 days/year. M/L/A (PCO) and farmers' employees were assumed to work 8 hours/day, 8 days/17-day season, and 16 days/year. Pilots, loaders, and flaggers (aerial application of granules) were assumed to work 4 hours/day, 8 days/17-day season, and 8 days/year. M/L/A for the center-pivot irrigation system was assumed to work 2 hours/day, 6 days/17-day season and 6 days/year.

M/L and A wore flannel shirts with the sleeves rolled up, jeans, boots, caps, sunglasses; long rubber gloves were worn only during mixing/loading. A M/L/A wore a long-sleeved shirt, long pants, rubber boots; additionally mid-forearm length gloves and a hard hat with a protective face shield were worn during mixing/loading.

^c MOS = NOEL (μ g/kg/day) ÷ absorbed dosage (μ g/kg/day).

dermal exposure was the sum of dermal exposures of hands, unclothed skin areas (face, back and front of the neck), and clothed skin areas (except for (f) where body exposure was not measured and was not included).

^e dietary exposure was estimated by the Medical Toxicology Branch, Department of Pesticide Regulation.

^g exposure was estimated based on clothing protection provided by long-sleeved shirt, long pants, rubber gloves, shoes plus socks.

Table 2. Mitigated EPTC exposure for mixer/loaders, applicators, mixer/loader/applicators, farmers' employee, and flaggers^a

	F	Exposure/ ₁	person			
		(µg/work	•	(μ	g/kg/day)	
		n-mitigato ADD (MO	ed Mitigated (S)	Al	OD (MOS)	SADD (MOS)
A. Liquid formul	ation: groun	d applicat	ion			
M/L	Dermal	7332	4021	10.48	4.32	0.20
	Inhalation	600	60	0.43	0.18	0.01
	Dietary			1.20	1.20	0.50
	Total	7932	4081	12.11 (1651)	5.69 (123	0.71 (705)
A	Dermal	6244	745	1.94	0.80	0.04
	Inhalation	532	532	3.80	1.56	0.07
	Dietary			1.20	1.20	0.50
	Total	6776	1277	6.94 (2881)	3.56 (196	0.61 (820)
	M/L/A (PC	O)				
$M/L/A^b$:as M/L	Dermal	1217	141	10.43	4.30	0.20
(PCO)	Inhalation	195	19.5	1.77	0.73	0.03
	Dietary			1.20	1.20	0.50
	Total	1412	160.5	13.40 (1492)	6.22 (112	0.73 (681)
:as A	Dermal	26411	3861			
	Inhalation	2285	229			
	Total	28696	4089			
	M/L/A (Fai	mers' em	ployee)_			
Farmers' :as M/L	Dermal	1217	141	10.43	4.30	0.20
employee ^c 0.03	Inl	nalation	195	19.5	1.77	0.73
(M/L/A)	Dietary			1.20	1.20	0.50
(IVI/ L// I)	Total	1412	160.5	13.40 (1492)	6.22 (112	
:as A	Dermal	26411	3861			
	Inhalation	2285	229			
	Total	28696	4089			
B. Granular form	ulation: B.1	flowers/o	ornamentals			
L/A	Dermal	4840	4840	12.62	5.20	0.24
	Inhalation	240	240	1.71	0.71	0.03
	Dietary ^e			1.20	1.20	0.50
	Total	5080	5080	15.53 (1288)	7.10 (99)	0.77 (645)

Table 2 (cont.). Mitigated EPTC exposure for mixer/loaders, applicators, mixer/loader/applicators, farmers' employees, and flaggers

	E	Exposure/p	person				
		(µg/work	(day)	(µg	(µg/kg/day)		
	No	n-mitigate	ed Mitigated	AD	D (MOS)	SADD (MOS)	
	AA	ADD (MO	S)				
B. Granular form	ulation. B.2	aerial app	<u>olication</u>				
Pilots	Dermal	676	Exposure mitigation is not needed.				
	Inhalation	220					
	Dietary						
	Total	896					
Flaggers	Dermal	5772	852	2.22	0.91	0.04	
	Inhalation	244	244	1.74	0.72	0.03	
	Dietary			1.20	1.20	0.50	
	Total	6017	1096	5.16 (3874)	2.83 (247)	0.58 (868)	
Loaders	Dermal	21202	4262	11.11	4.58	0.21	
	Inhalation	4180	418	2.99	1.23	0.06	
	Dietary			1.20	1.20	0.50	
	Total	25382	4680	15.30 (1307)	7.01 (100)	0.77 (649)	
C. Chemigation.	C.1 water-ru	un					
Loaders	Dermal	2354	Exposure mitigation is not needed.				
	Inhalation	60	1	C			
	Dietary						
	Total	2414					
C. Chemigation.	C.2 center-r	oivot sprin	ıkler system				
M/L/A	Dermal	84400	18940	49.38	5.81	0.27	
	Inhalation	138	13.8	0.10	0.01	0.001	
	Dietary			1.20	1.20	0.50	
	Total	84538	18954	50.68 (395)	7.02 (100)		

^a requirements for PPE and specific duration and frequency of exposure are shown in Table 3.

b exposure estimate for M/L was obtained from a study conducted by Ross *et al.*, (1986); whereas, the applicator exposure was obtained from the exposure estimate for M/L/A (Knarr and Iwata, 1986) minus the above M/L exposure estimate. The exposure time is one hour per day for M/L and that for A is seven hours.

c same PPE are required as in (b). Exposure estimates for M/L and A were derived as in (b).

Table 3. PPE and specified duration and frequency of exposure required to mitigate EPTC exposure^a

Work task	Hours/	Workdays/ 17-D season	Workdays	Required PPE ^b
WOIK task	workday	17-D season	year	Required FFE
M/L-ground (Liq)	4	7	7	Coverall, half-face respirator
Loader-aerial (G)	4	7	7	Coverall, half-face respirator
A-ground (Liq)	8	7	7	Coverall
M/L/A (PCO) (Liq)	8	7	7	Coverall, half-face respirator
M/L/A (grower) (Liq)	8	7	7	Coverall, half-face respirator
Flagger-aerial (G)	8	7	7	Coverall
M/L/A (center-pivot)	2	2	2	Rainsuit, half-face respirator
A-ground (G)	8	7	7	No. Reduced workdays
Water-run chem. (Liq)	8	7	7	No exposure mitigation
Pilot-aerial (G)	8	7	7	No exposure mitigation

M/L = mixer/loader; A = applicator; D = day; Liq = liquid formulation; G = granular formulation.

- a) Liquid formulation: Long-sleeved shirt, long-legged pants, chemical-resistant or water-proof gloves, shoes plus socks, and protective eyewear.
- b) Granular formulation: Long-sleeved shirt, long-legged pants, water-proof gloves, shoes plus socks

Table 4. Default protective values (Thongsinthusak *et al.*, 1993) employed in exposure mitigation

Mitigation option	Percent protection	n Exposure route/area
Chemical-resistant gloves	90%	hand exposure
Coverall	90%	chest, back, arms, thighs, and legs
Full-body chemical-resistant protective sui	it 95%	dermal to clothed areas (assume to cover 75% of unclothed areas)
NIOSH/MSHA approved half-face respira	tor	90% inhalation exposure

^a product labels require the following clothing for handlers:

^b in addition to those requirements as indicated in (^a).

Calculation of mitigated exposure:

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\begin{array}{lll} ADD \ (\mu g/kg/day) &=& [(A+B) \div body \ weight \ (70 \ kg)] + C \\ SADD \ (\mu g/kg/day) &=& ADD \ x \ workdays/season \div 17 \ days/season \\ AADD \ (\mu g/kg/day) &=& ADD \ x \ workdays/year \div 365 \ days/year \end{array}
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Where:

- $A = Dermal\ exposure\ (\mu g/person/day)\ x\ (100\ -\ \%\ default\ protective\ value)\ x\ \%\ dermal\ absorption\ (18.25\%)$
- $B = Inhalation \ exposure \ (\mu g/person/day) \ x \ (100 \% \ default \ protective \ value) \ x \ \% \ inhalation \ uptake/absorption \ (50 \ \%)$
- $C = Dietary exposure (\mu g/kg/day)$

(TCW/Mitigate/HSM-98002)